Notice of Allowability	Application No.	Applicant(s)	
	09/771,161	LEVINE ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amdt of November 4, 2004*.

2. ☒ The allowed claim(s) is/are *3,12 and 33*.

3. ☒ The drawings filed on *26 January 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
      1. ☒ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 1104
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Applicant's response, on November 4, 2004, to the First Action on the Merits of this case mailed May 5, 2004, is acknowledged. It is acknowledged that applicants have cancelled Claims 13 and 14 and amended Claims 3, 12, and 33. Claims 1-12 and 15-35 are pending. Claims 1, 2, 4-11, 15-32, 34, and 35 were withdrawn from further consideration in the First Action on the Merits. Claims 3, 12, and 33 are hereby reconsidered.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Claims

Cancel Claims 1, 2, 4-11, 15-32, 34, and 35.

Replace Claims 3, 12, and 33 with the following.

Claim 3. An isolated polypeptide selected from the group consisting of:

(i) the polypeptide encoded by the isolated nucleic acid sequence of SEQ ID NO: 2; and

(ii) the polypeptide set forth by SEQ ID NO: 93.

Claim 12. A pharmaceutical composition comprising a pharmaceutically acceptable carrier and, as an active ingredient, the polypeptide of Claim 3.

Claim 33. An inhibitor of kinase activity comprising the polypeptide of Claim 3.

Authorization for this examiner's amendment was given in a telephone interview with Marc Weiner's representative, Christy Rupert, on February 8, 2005.

Allowable Subject Matter

Claims 3, 12, and 33 are allowed.

The following is an examiner's statement of reasons for allowance:

All elected Claims, 3, 12, and 33, are limited to the isolated polypeptide as encoded by SEQ ID NO: 2 and as set forth by SEQ ID NO: 93. The specification asserts that said polypeptide has utility as a dominant negative inhibitor of the enzymatic activity of a protein kinase. Said asserted utility is credible based on the following. The polypeptide of SEQ ID NO: 93 has 100% identity with residues 314-540 of the protein kinase RICK, as taught by Inohara et al, 1998. RICK is composed of an N-terminal serine-threonine kinase catalytic domain and a C-terminal region containing a caspase-recruitment domain. Thus, the polypeptide of SEQ ID NO: 93 comprises the caspase-recruitment domain but not the catalytic domain. A person of ordinary skill in the art would know that the polypeptide of SEQ ID NO: 93 would be able to bind to RICK targets but not have enzymatic activity and, therefore, would act as a dominant negative inhibitor of RICK. The teachings of Inohara et al, 1998 further support the utility of the protein set forth by SEQ ID NO: 93 as a dominant negative inhibitor of RICK. Inohara et al, prepared a RICK variant in which the ATP-binding site at residue K^{38} was mutated to methionine. Said variant is enzymatically inactive (Fig 3D) and functions as a dominant negative inhibitor of RICK (Fig 3C). Like the variant of Inohara et al, the protein of SEQ ID NO: 93 has the C-terminal caspase-recruitment domain but is enzymatically inactive and thus, like said variant, the protein of SEQ ID NO: 93 would function as a dominant negative inhibitor of RICK.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Sheridan Lee Swope, Ph.D.

TEKCHAND SAIDHA
PRIMARY EXAMINER